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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,277	03/06/2002	Thomas Ehrhardt	50716	2896
26474 7590 01/12/2007 NOVAK DRUCE DELUCA & QUIGG, LLP 1300 EYE STREET NW SUITE 1000 WEST TOWER WASHINGTON, DC 20005			EXAMINER SAIDHA, TEKCHAND	
			ART UNIT 1652	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	
3 MONTHS			01/12/2007	
			DELIVERY MODE	
			PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/070,277

Applicant(s)

EHRHARDT ET AL.

Examiner

Tekchand Saidha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9,10,14,19-21 and 24-34 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 24-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-34 is/are rejected.
- 7) ☒ Claim(s) 9,10,14,19 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Office Action

1. In response to the prior Final rejection (mailed on 9/12/2006), Applicants filed a request for continued examination (RCE) and an amendment on December 1, 2006. Said amendment added new claims 24-34. Thus, Claims 9-10, 14, 19-21 & 24-34 are pending.

2. Claims 9-10, 14, 19-20 and 33-34, drawn to originally elected invention of Group III are under consideration in this OFFICE ACTION. See Applicants' response filed to restriction requirement on July 26, 2004.

3. Claims remain withdrawn :

Claims 21 & 24-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. New claims 21 & 24-32 are directed to 'a method of screening herbicidally active substances ---using 'dihydroorotase or a protein having dihydroorotase activity', which does not require the DNA for its production, as required in the originally elected method claim. The invention of claims 21 & 24-32 is therefore distinct as not requiring the recombinant production of dihydroorotase as compared to the instantly prosecuted invention requiring the recombinant production of dihydroorotase.

4. Claims 9-10, 14, 19-20 and 33-34 are under consideration in this examination.

5. Applicant's arguments filed 12.01.2006 have been considered and not found to be persuasive. The reasons are discussed following the rejection(s).

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6. Any objection or rejection of record which is not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn.

7. Claims 9-10, 14, 19-20 and 33-34 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims depend upon non-elected invention.

8. Claim Rejections - 35 USC § 112, first paragraph (Enablement)

Claims 33-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method (or process) for screening herbicidal active substances by inhibiting the activity of a plant dihydroorotase, comprising producing dihydroorotase recombinantly using the DNA sequence of SEQ ID NO: 1, does not reasonably provide enablement for using any DNA sequence having at least 40% homology to SEQ ID NO: 1 and which encodes a protein having the enzymatic activity of a dihydroorotase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 33-34 are so broad as to encompass a method of identifying an inhibitor of any dihydroorotase, which is encoded by a DNA having at least 40% identity to SEQ ID NO: 1. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of dihydroorotase broadly encompassed by the claims.

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Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide sequence of SEQ ID NO: 1 and encoded amino acid sequence of dihydroorotase of SEQ ID NO: 2.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications of any dihydroorotase by modifying the DNA to have a homology of at least 40% to SEQ ID NO: 1, because the specification does not establish: (A) regions of the protein structure which may be modified without effecting dihydroorotase activity; (B) the general tolerance of dihydroorotase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any

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dihydroorotase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including dihydroorotase with an enormous number of amino acid modifications of the of SEQ ID NO: 2 [as a result of modifying the DNA]. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of dihydroorotase(s) having the desired biological characteristics, and further use in the method for identifying herbicidal compounds is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Applicants' arguments (previous):

9. Claims 9-10, 14 and 19-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Tekchand Saidha

Primary Examiner, Art Unit 1652

Recombinant Enzymes, 02A65 Remsen Bld.

400 Dulany Street, Alexandria, VA 22314

Telephone : (571) 272-0940

January 4, 2007